



BILLING CODE: 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Toxic Substances and Disease Registry

[60Day-15-0046; Docket No. ATSDR-2015-0005]

**Proposed Data Collection Submitted for Public Comment and
Recommendations**

AGENCY: Agency for Toxic Substances and Disease Registry
(ATSDR), Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Agency for Toxic Substances and Disease Registry (ATSDR), as part of its continuing efforts to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995 (PRA). This notice invites comment on the three-year extension of information

collection clearance for the "Prospective Birth Cohort Study Involving Environmental Uranium Exposure in the Navajo Nation" project (OMB Control No. 0923-0046; expiration date 05/31/2016). The purpose of the study is to examine the potential association between environmental contaminants (i.e., uranium and other heavy metal exposures) and reproductive birth outcomes by recruiting Navajo mothers to assess and follow theirs and their children's uranium exposures at birth and at key developmental milestones.

DATES: Written comments must be received on or before

[INSERT DATE 60 DAYS AFTER PUBLICATION DATE IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments, identified by Docket No. ATSDR-2015-0005 by any of the following methods:

- Federal eRulemaking Portal: [Regulation.gov](http://www.regulation.gov). Follow the instructions for submitting comments.
- Mail: Leroy A. Richardson, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS-D74, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. All relevant comments received will be posted without change to [Regulations.gov](https://www.regulations.gov), including any personal information provided. For access to the docket to read background documents or comments received, go to [Regulations.gov](https://www.regulations.gov).

Please note: All public comment should be submitted through the Federal eRulemaking portal ([Regulations.gov](https://www.regulations.gov)) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact the Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS-D74, Atlanta, Georgia 30329; phone: 404-639-7570; E-mail: omb@cdc.gov.

SUPPLEMENTARY INFORMATION:

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In

addition, the PRA also requires Federal agencies to provide a 60-day notice in the Federal Register concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, disclose or provide

information to or for a Federal agency. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information; and to transmit or otherwise disclose the information.

Proposed Project

Prospective Birth Cohort Study Involving Environmental Uranium Exposure in the Navajo Nation (U01), (OMB Control No. 0923-0046, Expiration Date 02/29/2016) - Extension - Agency for Toxic Substances and Disease Registry (ATSDR).

Background and Brief Description

The Navajo Nation is the largest Alaska Native/American Indian Reservation in the United States. From 1948 to 1986, many uranium mining and milling operations took place in the Navajo Nation, leaving a large amount of uranium contamination on the reservation. The

House Committee on Oversight and Government Reform requested that federal agencies develop a plan to address health and environmental impacts of uranium contamination in the Navajo Nation.

As a result in 2013, ATSDR and its research partners (University of New Mexico Community Environmental Health Program [UNM-CEHP], Navajo Area Indian Health Service [NAIHS], Navajo Nation Division of Health [NNDOH], Navajo Nation Environmental Protection Agency [NNEPA], and Navajo culture and language specialists) initiated a research study titled "Prospective Birth Cohort Study Involving Environmental Uranium Exposure in the Navajo Nation" (OMB Control No. 0923-0048; expiration date 02/29/2016). The goal of the research is to better understand and prevent unfavorable child and maternal health outcomes potentially related to prenatal exposures to uranium. As ATSDR has received supplemental funding to continue the study, a three-year extension for PRA clearance is requested to allow further recruitment of mother-infant pairs.

Participants include Native American mothers from age 14 to 45 with verification of pregnancy who have lived in the study area for at least 5 years. Also, participants must consent to receive prenatal care and deliver at one of

the healthcare facilities that are taking part in the study.

Since 2013, over 525 mother-infant pairs and over 160 fathers have been enrolled. Biological sample analysis, surveys, and developmental screenings are performed during for each participant. An estimated 675 biomonitoring samples have been analyzed for 36 metals/metalloids including uranium, arsenic, lead and mercury. Home environmental assessments (HEAs) consist of gamma radiation surveys, indoor air radon tests, and dust sample analysis of the participants' primary residence during pregnancy, and over 400 HEAs have been completed to date. Study participants receive report back letters on their biomonitoring and HEA results to inform them of uranium and other heavy metals in their bodies and in and around their home environment.

The survey instruments for pregnant mothers include the following: Enrollment Survey, Ages and Stages Questionnaire (ASQ-I), Mullen Stages of Early Development (MSEL), Postpartum Surveys, and Food Frequency Questionnaire/WIC Intake. An enrollment survey for fathers who agree to participate is also administered. Follow-up assessments including the Ages & Stages Questionnaire and biomonitoring at 2, 6, 9 and 12 months are currently being

conducted for the 387 infants delivered to date.

Community Health and Environmental Research Specialists (CHERS) administer the surveys using a CDC-approved electronic data entry system. Survey instruments are used to collect demographic information and to assess potential environmental health risks and mother-child interactions. The final format of the survey instruments is based on review and input from the Navajo Nation community liaison group and associated Navajo staff to address issues such as cultural sensitivity, comprehension and language translation.

There is no cost to the respondents other than their time to participate in the study. The total estimated annual burden hours equals 4,455.

Estimated Annualized Burden Hours

Type of Respondents	Form Name	No. of Respondents	No. of Responses per Respondent	Avg. Burden per Response (in hrs.)	Total Burden (in hrs.)
Mother	Eligibility form (screening form)	750	1	5/60	63
	Enrollment Survey	550	1	2	1,100

	Home environm ental assessme nt	550	1	1	550
	Ages and Stages Question naire - (2, 6, 9, 12) months	500	4	15/60	500
	Mullen Stages of Early Developm ent	500	1	20/60	167
	Postpart um Survey (2 months)	500	1	1	500
	Postpart um survey - (6, 9, 12 months)	500	3	15/60	375
	Food Frequenc Y Question naire/WI C Intake	500	1	45/60	375
Father	Enrollme nt survey	550	1	90/60	825
Total					4,455

Leroy A. Richardson
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Office of Scientific Integrity

Office of the Associate Director for Science
Office of the Director
Centers for Disease Control and Prevention

[FR Doc. 2015-24718 Filed: 9/29/2015 08:45 am; Publication
Date: 9/30/2015]